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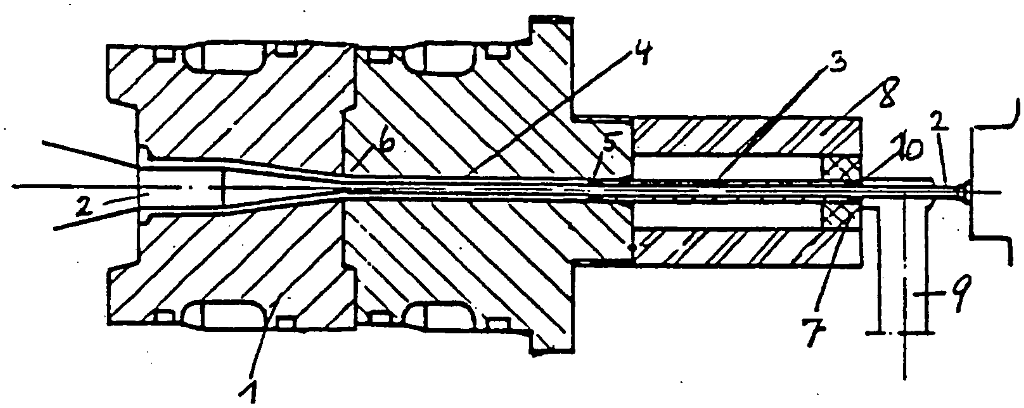
(54) Title: A PROCESS FOR PRODUCING THIN WALLED TUBES WITH CONNECTING ELEMENTS BY INJECTION MOULDING, THE TUBES THUS PRODUCED AND THEIR USE AS INDWELLING VEIN CANNULAS



(57) Abstract

A process for producing cylindrical, thin walled tubes having a length of 10 to 150 mm and an outer diameter of maximum 2.5 mm and a wall thickness of 0.08 to 0.50 mm with a connecting means by injection moulding, whereby the core (2) of the mould for holding the tube open within the mould is centered by means of a movable sleeve (3).

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A process for producing thin walled tubes with connecting elements by injection moulding, the tubes thus produced and their use as indwelling vein cannulas

The invention relates to a process for producing thin walled tubes having a connecting element at one end by injection moulding and such tubes, which can also be used as indwelling vein cannulas.

The production of thin walled tubes, for example plastic tubes, by extrusion, is basically known. In order to provide pieces of such tubes with connecting elements or particularly constructed ends, additional courses of manufacture are required, which are labour- and cost-intensive.

DE-A-14 79 363 describes the production of a plastic cannula, where a hollow needle is dipped into liquid resin and subsequently hung up by the tip so that the resin flows downwards due to the force of gravity and the cannula is formed having an increasingly thicker wall toward the grip.

From DE-A-37 23 318 an indwelling vein cannula is known, which is produced from a seamless tube of polypropylene, and where the connecting element with grip plate at one end is subsequently gated.

The injection moulding of complicated shapes and hollow products has been known for a long time.

Described in DE-A-34 43 723 is a device and a method for producing plastic tubes of more than 50 cm in length and having a length:diameter ratio of 10:1, where the core is drawn out of the mould before the plastic material shrinks on cooling. This enables the tube to be removed from the mould after shrinking without the outer surface being damaged. A

one piece mould can be used, so that the tubes have no visible seams, as can occur with composite hinged moulds.

The production of cylindrical capillaries with wall thicknesses of about 0.15 mm and with an internal diameter of 1 mm and a length of the order of 50 mm or more by means of injection moulding has hitherto been impossible because of the flow problems in this production technique.

The object of the invention is to provide a process for producing thin walled tubes by injection moulding, which enables thin walled tubes of a specific length to be produced in one piece and thereby simultaneously forming a connecting means.

The object is achieved by the process for producing thin walled tubes having a connecting means by injection moulding, characterized in that cylindrical, thin walled tubes of a length of from 10 to 150 mm and a maximum outer diameter of 2.5 mm and a wall thickness of from 0.08 to 0.50 mm are produced in one piece by injection moulding, and in order to keep the tube open within the mould, the core of the mould is centered during injection moulding by a movable sleeve, which can be moved along the tube axis, the outer diamter of which is at least 1 μm smaller than the inner diameter of the mould for the hollow cylindrical tube, whose inner diameter is at least 1μm larger than the outer diameter of the core of the mould, whereby the sleeve, during the introduction of the the tube material into the mould, is moved by the material in the annular cavity between the mould and the core from the start of the hollow cylindrical annulus at the transition to the connecting means, towards the mould end, and the retraction of the sleeve is co-ordinated with the introduction of the tube material into the mould by blocking the axial movability of the sleeve during the injection phase until the flow front of the material has almost reached the sleeve and only then letting the retraction of the sleeve commence by removing the block and co-or-

dinating the injection pressure and speed of the material with the pressure resistance of the sleeve.

The movability of the sleeve towards the axis of the tube is effected by the pressure wave in front of the flow front of the injected material. Thus the material can either immediately affect the sleeve, or it can do so via a gas cushion formed between the flow front and the sleeve.

Preferred wall thicknesses for the hollow cylindrical part of the tube are from 0.1 to 0.25 mm. The sleeve has preferably an outer diameter of 10 to 30 μm less than the inner diameter of the mould for the hollow cylindrical part of the tube whose inner diameter is 10 to 30μm greater than the outer diameter of the core. It is essential, that the sleeve can be easily moved on the core within the mould, but however, the centering effect is retained, i.e. the free space between the sleeve and the mould, resp. core is kept to a minimum only just permitting movement.

It was completely unexpected, that this technique enables thin walled tubes to be produced of a precision and form hitherto held for impossible by injection moulding, making finishing of the tubes generally superfluous.

Preferably, as connecting means a ring flange is simultaneously formed at one tube end. In a different embodiment of the invention at one of the tube ends a connector Luer-Lock LLS with an internal cone complying with DIN 13090 is formed.

By using a sleeve, whose front surface facing the front of the material is structured in a particular manner, or has a profile, the tip of the tube can simultaneously be shaped as desired. It is for example possible to form a so-called bevel or conical tip at the front end of the tube, by using a sleeve, whose inner diameter over the length of the desired tip has been altered so that the material can also enter into the space between the core and the inner surface of the

sleeve in the area of its increased inner diameter.

Such a tip to the tube can for example have a wall thickness of 0.035 mm to 0.06 mm. The preferred angle for the chamfered edge of the tip is from 25° to 35°, whereby a radius of curvature for the chamfered edge of less than 0.13mm is preferred. The tip may have a length of between 2 mm and 5 mm.

The inner diameter of the externally conically tapered tip is preferably 10 to 20% less than the inner diameter in the hollow cylindrical part. The transition takes place at the end of the hollow cylindrical part at the externally conically tapered tip or near the start of the conical tip. The transition point can also be designed as a stage on the inner wall.

To improve the resistance of the tube to kinking in the area of the connecting element, it is then particularly preferred, if the connecting element is constructed as a connector Luer-Lock with an internal cone complying with DIN 13090, a transition from the hollow cylindrical part of the tube to the connecting element is constructed over a length of between 4 mm and 15 mm, preferably 3 mm to 8 mm, and within this area the outer diameter of the tube and the wall thickness of the material is continuously increased until the outer diameter is 2.5 mm to 5 mm and the wall thickness 0.8 to 2.0 mm. This strengthening of the tube wall can also be effected for different connecting elements in order to increase the resistance to kinking in the connecting element area. The connectors LLS according to DIN 13090 have an internal cone tapered from 1:16 2/3, and at the rear end for locking the connecting lines to two portions of the outer circumference, there are protrusions, which are also known as wings. The dimensions of such cone connections are also described in the international standard ISO 594 parts 1 and 2.

Metals suitable for injection resp. cast moulding are alloys

of zinc, magnesium, aluminium and copper.

Plastics suitable for injection moulding are thermoplastics, such as polyolefines, in particular low density polyethylene (LDPE), or polypropylene, polyamide, polyurethanes, polyvinyl chloride, synthetic and thermoplastic rubbers or mixtures thereof. Both homopolymers and copolymers of two or more monomers are suitable. The thermoplastics should be free flowable and thus have the preferred melt flow indices of greater than 15 g/10 mins. (MFI190/2,16 according to DIN 53 735). Most preferred are polymers having a melt flow index of 17 - 25 g/10 minutes. As plastics, qualities can be selected, which are medically compatible.

These particularly good flow properties of the polymers can be attained by suitable molecular weight distribution and ratios of average weight of the molecular weight (Mw) to the average number of the molecular weight (Mn). They can also be obtained by specific copolymerisation conditions, such as the formation of block copolymers or graft copolymers from two or more monomers. The particular flow properties can also be based on mixtures of polymers or incorporation of polymeric particles in a polymer matrix.

The problem with the production of hollow cylindrical tubes having a length of 10 mm to 150 mm, preferably up to 100 mm by injection moulding lies in that for thin walled parts, i.e. wall thicknesses of less than 0.3 mm down to 0.08 mm, the core of the mould holding the interior of the hollow cylinder open during injection moulding has to be precisely centered, since only slight deviations from the coaxial position leads to irregular wall thicknesses of the tube and irregular material flow within the mould. This, however, is necessary for preferred wall thicknesses of the tube of 0.1 mm to 0.2 mm.

The centering is effected according to the invention by a sleeve which is movably located in the annular space between

the mould and the core, which has a clearance of at least 1 μm, preferably 1μm to 50 μm, most preferred 10 to 30 μm between the parts (mould and core), in order to be easily moved.

Besides its centering effect, the sleeve also provides for an even progression of the flow front of the material injected into the cavity. It is essential that the receding of the sleeve caused by the material flow in the cavity is controlled, whereby the tube material has to overcome a resistance greater than the frictional resistance of the sleeve. This resistance and its dependency on time is, according to the invention, coordinated with the introduction of the material to the mould and is deliberately controlled in order to improve the flow of the tube material in the cavity. Initially, the end of the sleeve facing the flow front of the material is located at the transition point of the mould to the hollow cylindrical part, and the other end of the sleeve extending beyond the mould is blocked against axial displacement. The flow front of the material can be detected by a sensor located in the mould, so that when the flow front of the material has reached the end of the sleeve or almost reached the end, the sleeve is released for movement in axial direction. The release can also be dependent on time from the start of the injection procedure. The sleeve is then pushed in axial direction by the pressure wave of the flow front on the core from the mould. Thus a defined resistance is set, so that a pressure of approximately 0.2 bar or less has to be overcome. The sleeve is formed longer than the mould, so that the braking of the sleeve for creating the resistance is carried out by means of a hydraulic or pneumatice device, which is applied to the rear end of the sleeve. By this device, pressure is applied in axial direction to the sleeve in order to convey it back for the next injection cycle in the annulus between the mould and the core, into its starting position. The cycle periods are usually 10 to 15 seconds long. After the sleeve has completed its movement in axial direction it should preferably be additionally suppressed in its movement.

This can be effected either by air or hydraulically by appropriate devices implemented at the rear end of the sleeve, extending beyond the mould.

The easiest way of controlling is to increase the sleeve's braking resistance of friction during the injection of material into the cavity shortly before completion of the injection procedure.

By using a mould with several cavities for the simultaneous production of several tubes it is preferred that the injection into each cavity is controlled independently of that into the other cavities, in order to attain the desired exactness of the precision injection mould. For coordinating the introduction of the material and the retraction of the sleeve, computer controller injection moulding machines are preferred where the process can be progammed and split into numerous individual steps. Such machines are commercially available from various companies.

After completion of the injection procedure and cooling of the material to a temperature below the thermoplastic range, the mould is opened and the tube removed from the core. After closing the mould and conveying the sleeve to its starting position, the next injection cycle can commence.

When using medically compatible plastics as the material for the thin walled tubes to be produced according to the invention these can be employed as indwelling vein cannulas. This is why the invention also includes cylindrical indwelling vein cannulas made of plastic having a bevelled tip and a connecting portion at the rear end. They are produced in one piece by injection moulding and the hollow cylincrical part preferably has a length of 20 to 100 mm, and outer diameter of maximum 2.5 mm and a wall thickness of 0.8 to 0.25 mm, as well as an externally, conically tapered tip, the wall thickness at the front end being 0.035 to 0.06 mm, and a connecting means at the rear end having an inner cone with a

greater wall thickness. The connecting means preferred is a connector Luer-Lock LLS having an internal cone according to DIN 13090.

A more detailed description of the invention is given with reference to the figures.

Figure 1 shows a longitudinal section of the suitable mould for carrying out the process, which is used with injection moulding machines available on the market.

2igure 2 shows an enlarged longitudinal section of a thin walled tube with connecting element.

Figure 3 shows an enlarged longitudinal section of the embodiment of a conically tapered tip at the front end of the tube.

Figure 1 is the device in longitudinal section for the method according to the invention with a mould 1 and a core 2 located therein. The sleeve in the annulus 4 of the hollow cylindrical mould, movable between the mould and the core 2 is depicted as 3. After the polymeric material has been removed from the mould, which is then closed, this sleeve is still in a receded position and has to be conveyed still further into the annulus before the new cycle can commence, till its front end 5 is located at the transition point, to the reinforcing region, shown as 6. At the rear end of the sleeve 3 a bearing bush 7 is mounted, which can be slided in a hollow cylinder 8. The devices for holding the sleeve 3 and the hydraulic or pneumatic means can, for example, act upon the bearing bush 7, so that the bearing bush 7 is moved with the sleeve, resp. suppressed.

The core 2 can be supported at the rear end of the mould. In the figure a connection means 9 to a pneumatic valve is outlined as an example for pneumatic devices for operating at the rear end 10 of the sleeve 3.

Figure 2 shows an enlarged longitudinal section of a thin walled tube 11 produced according to the invention, with a transition range 12 and a connecting portion 13, which is constructed as a connector Luer-Lock with internal core according to DIN 13090.

Figure 3 shows an enlarged longitudinal section of a tip 14, which is connected to the hollow cylindricyl portion 11. The inner diameter of the hollow cylindrical part 11 is larger than the inner diameter 16 at the tip. The transition 15 is effected at the end of or near the end of the hollow cylindrical part 11 and the beginning of the externally, conically tapered tip 14, whose front end 17 is even more bevelled to form an edge.

Example 1

A 6.25 mm long transition region is formed on a 25 mm long hollow cylindrical tube having an outer diameter of 0.8 mm and a wall thickness of 0.1 mm, where the wall thickness is increased to 2.0 mm. On to this a Luer-Lock connecter LLS, according to DIN 13090 having a length of 9 mm, is formed. At the end of the transition region the inner cone has a diameter of 3.8 mm and at the other end a diameter of 4.3 mm. Used as the material for the production by injection moulding is a suitable polyethylene having a melt flow index MFI 190/2, 16 (DIN 53735) from 17 to 22 g/10 minutes. The time taken for a cycle is 10 seconds. A computer controlled machine made by Battenfeld was used as the injection moulding machine. Along the plastifying path for the plastic and in the mould the temperature reached up to 250°C.

The tool or the mould with one cavity is outlined in Figure 1. The mould was opened after the polymer had cooled to below its glass transition temperature and the tube removed. The next cycle can be carried out after the mould has been closed, the temperature adjusted and the sleeve returned to its starting position.

Example 2

The production of an indwelling vein cannula from injection mouldable, medically compatible polyethylene having a melt index of 20 g/10 mins. (MFI 190/2, 16 according to DIN 53735) and a density of 0.918 g/cm³ at 23°C. The cannula has a 2.5 mm long hollow cylindrical portion including a 2.5 mm long externally, concically tapered tip. The inner diameter in the hollow cylindrical portion is about 0.64 mm and in the tip region about 0.54 mm. The wall thickness is about 0.21 mm in the hollow cylindrical portion and is reduced to 0.04 mm in the region of the tip. Connected to the rear end of the hollow cylindrical piece is a 6.25 mm long transition region, in which the inner diameter is continuously enlarged to 3.8 mm, and the wall thickness is increased to 2 mm. The rear end of the cannula is formed as a Luer connector LLS with an inner cone and is 9 mm long. The tapering of the cone complies with DIN 13090 amd from the end to the transition range is 1:16 2/3. The inner diameter at the rear end is 4.3 mm. Formed on the exterior of the end are two wings opposite each other, so that the outer diameter from the edge of one wing to the other is 7.7 mm. An injection moulding machine made by Battenfeld having a controllable injection operation is used. A temperature of from 210°C to 250°C is selected. The injection pressure is graduated at between 60 and 100 bar. The injection speed is also controlled during the cycle and altered.

The mould, core and sleeve are designed so that the aforementioned measurements are attained. The sleeve is guided and supported in a cylinder on the exterior of the mould, where the cylinder is attached to a pneumatic valve for applying braking force during the injection procedure and returning the sleeve to its starting position after the cylce has been completed.

The particular advantage of cannulas produced according to the invention is that no finishing, such as chamfering, bevelling and deburring, is necessary.

C L A I M S

1. A method for producing thin walled tubes having a connecting means by injection moulding, characterized in that cylindrical, thin walled tubes of 10 to 150 mm in length and having an outer diameter of maximum 2,5mm and a wall thickness of 0.08 to 0.50 mm are produced in one piece by injection moulding and the core of a mould for holding the tube open in the mould is centered during the injection moulding by a sleeve which can be moved along the tube axis having an outer diameter of at least 1 μm less than the inner diameter of the mould for the hollow cylindrical tube, and an inner diameter which is at least 1 μm larger than the outer diameter of the core of the mould, whereby the sleeve, during the introduction of the tube material into the mould, is pushed by the material in the annular cavity between mould and the core from the beginning of the hollow cylindrical annulus at the transition to the connecting means, towards the mould end, and the retraction of the sleeve is coordininated with the introduction of the tube material into the mould by blocking the axial mobility of the sleeve during the injection procedure until the flow front of the material has almost reached the sleeve and only then letting the sleeve recede by releasing the block and adjusting the injection pressure and speed of the material and the pressure resistance of the sleeve to each other.

2. The method according to claim 1, characterized in that a sleeve is used, which is longer than the mould and applied to the rear end of which, whilst it recedes in the cavity between the mould and the core, is a pneumatic or hydraulic braking force, so that the flow front of the injected mater-

ial has to overcome a pressure resistance of the sleeve of 0.1 to 0.2 bar and the pressure resistance is increased shortly before the end of the injection procedure to brake the axial movement of the sleeve at the end of the injection procedure.

3. The method according to claims 1 or 2,
c h a r a c t e r i z e d i n t h a t
at the rear end of the tube a ring flange is simultaneously formed as connecting means.

4. The method according to claims 1 or 2,
c h a r a c t e r i z e d i n t h a t
at the rear end of the tube a connection Luer-Lock LLS with internal cone according to DIN 13090 is formed as connecting means.

5. The method according to claims 1 or 2,
c h a r a c t e r i z e d i n t h a t
the transition from the hollow cylindrical tube to the connecting means is formed along a 4 mm to 15 mm section and in this region the outer diameter of the tube and the thickness of the wall continuously increase until the connecting means is reached, to an outer diameter of 2.5 mm and a wall thickness of 0.8 mm to 1.5 mm.

6. The method according to claims 1 or 2,
c h a r a c t e r i z e d i n t h a t
a sleeve is used, whose front end facing the material front has instead of a smooth surface a profile corresonding to the desired shape of the front end of the tube.

7. The method according to claim 6,
c h a r a c t e r i z e d i n t h a t
a sleeve is used, whose front end facing the material front is shaped as a 1 to 5 mm long inner cone having a decreasing diameter and thus forming at the front end of the tube an externally, conically tapered tip.

8. The method according to any of the claims 1 to 7, c h a r a c t e r i z e d i n t h a t a movable sleeve is used, whose outer diameter is 10 μm to 30 μm smaller than the inner diameter of the mould for the hollow cylindrical portion, and whose inner diameter is 10 μm to 30 μm larger than the outer diameter of the core.

9. The method according to any of the claims 1 to 8, c h a r a c t e r i z e d i n t h a t a mould having several cavities is used and the introduction of the material and the receding of the sleeve is independently controlled in each cavity.

10. The method according to any of the claims 1 to 9, c h a r a c t e r i z e d i n t h a t the sleeve is braked at the end of its path by air.

11. The method according to any of the claims 1 to 9, c h a r a c t e r i z e d i n t h a t the sleeve is braked at the end of its path hydraulically.

12. The method according to any of the claims 1 to 11, c h a r a c t e r i z e d i n t h a t the tube is formed out of plastic or a metal or metal alloy which is useable for injection or cast moulding.

13. The method according to claim 12, c h a r a c t e r i z e d i n t h a t the tube is formed out of thermoplastic polymers selected from polyolefines, polyamide, polyurethanes, polyvinyal chloride, synthetic and thermoplastic rubbers, or mixtures thereof.

14. A cylindrical indwelling vein cannula made of plastic produced according to claims 1 to 13, whereby the hollow cylindrical part has a length of from 30 to 100 mm, an outer diameter of maximum 1.3 mm and a wall thickness of from

0-08 mm to 0.20 mm, and an externally, conically tapered tip, the front end of which has a wall thickness of 0.035 to 0.06 mm and the rear end is formed as a connector Luer-Lock LLS with internal cone according to DIN 13090.

15. The indwelling vein cannula according to claim 14, characterized in that the tip has an edge chamfered at an angle of 25° to 35°.

Fig. 1

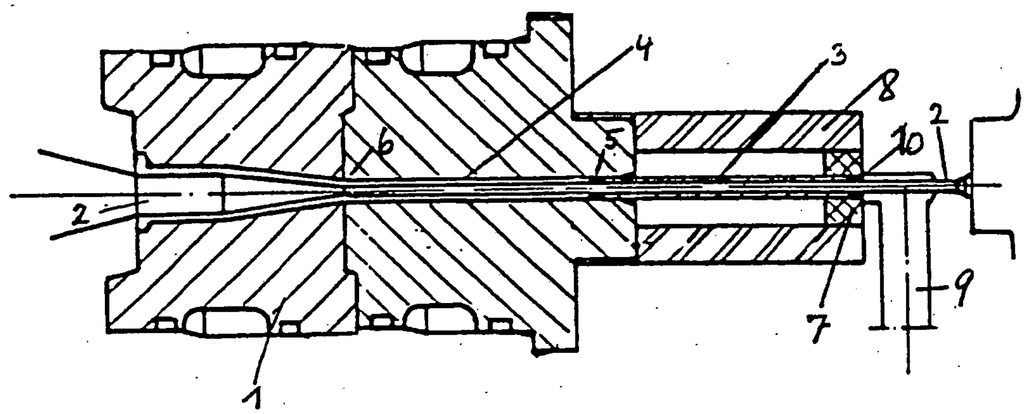


Fig. 2

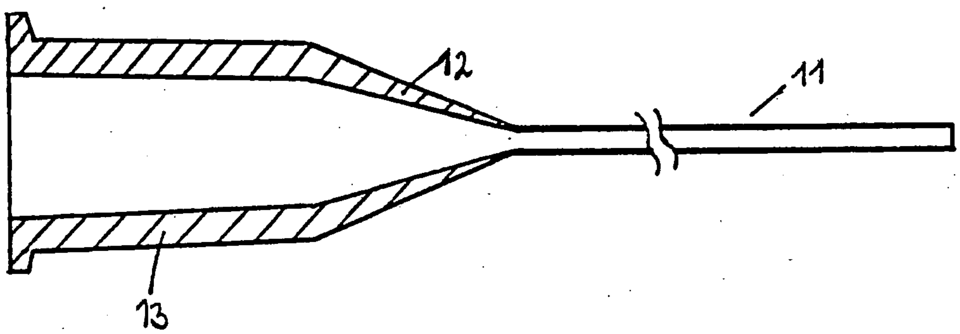
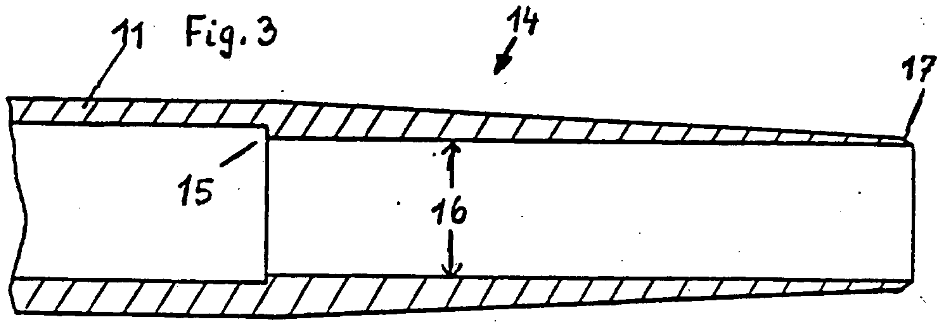


Fig. 3



INTERNATIONAL SEARCH REPORT

International Application No PCT/EP 89/00844

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 B29C45/36 ; A61M25/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	B29C ; A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
Y	US,A,4041122 (INTERNATIONAL PAPER CO.) 09 August 1977 see the whole document ---	1-4, 6, 8, 10-14
Y	US,A,4005166 (INTERNATIONAL PAPER CO.) 25 January 1977 see the whole document ---	1-4, 6, 8, 10-14
Y	GB,A,388662 (PHILIPS) 23 March 1933 see page 2, lines 69 - 94; figures 3, 4 ---	1, 12, 13
Y	FR,A,2055248 (VANOTTI) 07 May 1971 see the whole document ---	1, 2, 12, 13
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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
12 OCTOBER 1989	28. 11. 89
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	T.K. WILLIS

III. DOCUMENTS C NSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
Y A	GB,A,622207 (GRAVESEN) 26 May 1949 see the whole document ---	1, 2, 10-13 9
Y	US,A,3385553 (BRAUN) 28 May 1968 see the whole document ---	1, 4, 14

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

SA 30074

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report.
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FR-A-2055248	07-05-71	None	
US-A-3778211	11-12-73	None	
GB-A-622207		None	
US-A-3385553		None	

For more details about this annex : see Official Journal of the European Patent Office, No. 12/82